

Notice of Allowability	Application No.	Applicant(s)	
	10/014,812	PALMER ET AL.	
	Examiner	Art Unit	
	Samuel W. Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interview on 3/10/05.
2. ☒ The allowed claim(s) is/are 2,3 and 28.
3. ☒ The drawings filed on 14 December 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>3-10-05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Claims 2-3 and 5-30 are pending in the current application. Note that claims 1 and 4 are canceled by applicants' amendment filed 10/21/04. The following Office action is applied to the pending claims 2-3 and 5-30.

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a personal interview with Applicants' representative Teddy C. Scott, Jr. on March 10, 2005. Applicant agrees to cancel claims 5-27 and 29-30 without prejudice, and amend claims 2 and 3 (see below).

Amendments to the claim:

The pending claims 2-3 and 5-27 and 29-30 are amended as follows. Please replace the previous claims with the claims shown below.

Claim 2 (*Twice amended*): After administering" delete " a non-polypeptide cAMP level modulator wherein said cAMP level modulator is a phosphodiesterase" and before "inhibitor of a phosphodiesterase" add "an".

Claim 3 (*Twice amended*): Change "PDE4" to "phosphodiesterase type 4 (PDE4)".

Delete claims 5-27 and 29-30.

Amendments to the specification:

On paragraph [0001], line 2, after "09/928268" insert "(abandoned)".

In abstract, the last line, change "phosphodiesterase 4 isoforms" to "phosphodiesterase type 4".

Art Unit: 1653

The following is an **Examiner's Statement of Reasons for Allowance**: The interview with the applicants' representative on 3/10/05 has discussed the issues as follows. (1) Although patent 6423710 contains the motivation of using the PDE4 inhibitor in induction of ovulation, which is based on elevation of cAMP level by the inhibitor, within granulose cells, 6423710 does not fairly teach or suggest in vivo inducing ovulation in a female host by administering to the host the PDE4 inhibitor. Additionally, applicants point out that assumption made by the Tsafiriri' reference that suppression of cAMP-specific PDE may enhance the gonadotropin induction of ovulation is only limited to *in vitro* studies. Applicants stress that the Tsafiriri' reference does not teach in vivo application of the PDE inhibitory compound(s) to induce ovulation. (2) Before this invention, the field of PDE4 inhibitor confronts unpredictability, especially as to its roles in reproductive biology, e.g., Jin et al. (*Proc. Natl. Acad. Sci.* (1999) 96, 11998-12003, see the attached PTO-892) reference has indicated that the PDE4 knockout exhibits an impaired ovulation; and, on page 1324, Conti's Minireview reference (*Mol. Endocrinol.* (2000) 14, 1317-1327) has discussed that use of PDE indicators in endocrine cell responses (note that ovulation is one of such the responses) is an *unexplored* field. Therefore, applicants conclude that the obviousness rejection based on 6423710 lacks a reasonable expectation of success, which is the standard with which obviousness is determined. Accordingly, the Examiners have considered the above applicants' arguments and agree to withdrawn the rejection under 35 USC 103(a) in the Office action (final) mailed 12/23/04. Thus, claims 2, 3 and 28 are allowable over the art of record.

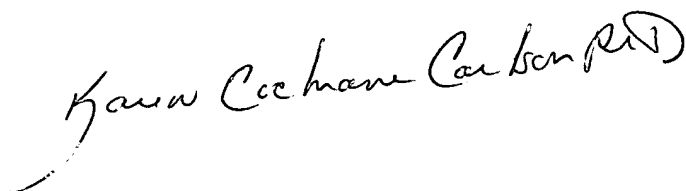
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (703) 306-3483. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (703) 308-2329. The official fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



Samuel W. Liu, Ph.D.

March 10, 2005

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER